

Application No.: 10/801,230  
Reply to Office Action of: August 29, 2005

### **IN THE CLAIMS**

Please amend the claims as follows, where added material is underlined and material to be deleted is indicated by strikethrough font. This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently amended) A device for electrical stimulation of a gastrointestinal tract of a patient, the device comprising:
  - a device housing sized for introduction into a gastrointestinal tract;
  - an electrical pulse generator, mounted within the device housing, to generate an electrical stimulation waveform;
  - a power source mounted within the device housing and coupled to the pulse generator;
  - one or more electrodes electrically coupled to the electrical pulse generator and mounted to the device housing to deliver the electrical stimulation waveform to the gastrointestinal tract;
  - and
  - a fixation structure to attach the device housing to a surface within the gastrointestinal tract wherein the fixation structure comprises an expandable frame mounted on the device housing that is expandable radially outward to contact a lumen wall within the gastrointestinal tract, a cavity formed within the device housing, or one or more barbed hooks extending from within the device housing to penetrate gastrointestinal tissue.
2. (Original) The device of claim 1, wherein the device housing has a substantially cylindrical capsule-like shape.
3. (Currently amended) The device of claim 1, wherein the fixation structure ~~includes a~~ comprises the cavity formed within in the device housing and further includes a pin to penetrate gastrointestinal tissue within the cavity.
4. (Original) The device of claim 3, wherein the cavity includes a vacuum port for application of vacuum pressure to draw the tissue into the cavity.
5. (Original) The device of claim 3, wherein the pin forms one of the electrodes.

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6. (Original) The device of claim 1, wherein the fixation structure includes two or more cavities, and vacuum ports for application of vacuum pressure to draw tissue into the cavities.
7. (Currently amended) The device of claim 1, wherein the fixation structure comprises ~~includes~~ one or more barbed hooks ~~that extend from the device housing to penetrate gastrointestinal tissue.~~
8. (Original) The device of claim 7, wherein the barbed hooks form at least one of the electrodes.
9. (Cancel) The device of claim 1, wherein the fixation structure includes a screw-like extension that extends from the device housing to penetrate gastrointestinal tissue.
10. (Cancel) The device of claim 9 wherein the screw-like extension forms one of the electrodes.
11. (Cancel) The device of claim 9, wherein the screw-like extension extends from a distal end of the device housing.
12. (Currently amended) The device of claim 1, wherein the fixation structure comprises ~~includes an~~ the expandable frame mounted on the device housing that is expandable radially outward to contact a lumen wall within the gastrointestinal tract, ~~and the device housing is mounted to the expandable frame.~~
13. (Cancel) The device of claim 1, further comprising a power source mounted within the device housing, and the power source is coupled to the pulse generator.
14. (Currently amended) The device of claim ~~1~~ 13, wherein the power source includes a substantially disc-shaped battery.

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15. (Original) The device of claim 1, wherein the fixation structure forms one of the electrodes.
16. (Original) The device of claim 1, wherein the electrodes include a first electrode and a second electrode mounted on an exterior surface of the device housing for electrical contact with tissue within the gastrointestinal tract.
17. (Original) The device of claim 1, wherein the device housing has a substantially cylindrical capsule-like shape, and at least one of the electrodes includes an electrode ring that extends about a circumference of the device housing.
18. (Original) The device of claim 1, wherein the device housing has maximum length of less than approximately 10 mm and a maximum width of less than approximately 5 mm.
19. (Original) The device of claim 1, wherein the fixation structure is degradable to permit detachment of the device housing from the tissue and passage of the device through the gastrointestinal tract.
20. (Original) The device of claim 1, wherein the pulse generator generates a stimulation waveform selected to suppress one or more symptoms including at least one of nausea and vomiting.
21. (Original) The device of claim 1, wherein the pulse generator generates a stimulation waveform selected to suppress one or more symptoms secondary to at least one of gastroparesis, functional dyspepsia, chemotherapy, post-operative ileus, and pregnancy.
22. (Original) The device of claim 1, wherein the pulse generator generates a stimulation waveform with an amplitude in a range of approximately 0.1 mA to 10 mA, a frequency in a range of approximately 10 Hz to 250 Hz, a pulse width in a range of approximately 100 microseconds to 1000 microseconds, an on duty cycle in a range of approximately 0.1 seconds to 0.5 seconds, and an off duty cycle in a range of approximately 1 second to 10 seconds.

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23. (Original) The device of claim 1, wherein the pulse generator generates a stimulation waveform with an amplitude of approximately 5 mA, a frequency of approximately 14 Hz, a pulse width of approximately 330 microseconds, an on duty cycle of approximately 0.1 seconds, and an off duty cycle of approximately 5 seconds.

24. (Original) The device of claim 1, wherein the device includes no leads that extend outside of a body of a patient upon placement of the device within the gastrointestinal tract.

25. (Currently amended) A device for electrical stimulation of a gastrointestinal tract of a patient, the device comprising:

a device housing sized for introduction into a gastrointestinal tract;  
means, mounted within the device housing, for generating an electrical stimulation waveform selected to suppress one of more symptoms of gastroparesis;  
means, mounted within the device housing, for supplying power to power the means for generating the electrical stimulation waveform;

one or more electrodes electrically coupled to the means for generating an electrical stimulation waveform and mounted to the device housing to deliver the electrical stimulation waveform to the gastrointestinal tract; and

means for attaching the device housing to a surface within the gastrointestinal tract, wherein the means for attaching comprises an expandable frame mounted on the device housing that is expandable radially outward to contact a lumen wall within the gastrointestinal tract, a cavity formed within the device housing, or one or more barbed hooks extending from within the device housing to penetrate gastrointestinal tissue.

26. (Currently amended) The device of claim 25, wherein the means for attaching ~~includes a~~ comprises the cavity formed in the device housing and further includes a pin to penetrate gastrointestinal tissue within the cavity, and wherein the cavity includes ~~including~~ a vacuum port for application of vacuum pressure to draw the tissue into the cavity.

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27. (Currently amended) The device of claim 25, wherein the means for attaching comprises ~~includes~~ one or more barbed hooks that extend from the device housing to penetrate gastrointestinal tissue.
28. (Cancel) The device of claim 25, wherein the means for attaching includes a screw-like extension that extends from the device housing to penetrate gastrointestinal tissue.
29. (Currently amended) The device of claim 25, wherein the means for attaching comprises ~~the includes an~~ expandable frame mounted on the device housing that is expandable radially outward to contact a lumen wall within the gastrointestinal tract, ~~and the device housing is mounted to the expandable frame.~~
30. (Cancel) The device of claim 25, further comprising means for supplying power to power the means for generating an electrical stimulation waveform, wherein the power supplying means is mounted within the device housing.
31. (Currently amended) The device of claim 25 ~~30~~, wherein the power supplying means includes a substantially disc-shaped battery.
32. (Original) The device of claim 25, wherein the means for attaching forms one of the electrodes.
33. (Original) The device of claim 25, wherein the device housing has maximum length of less than approximately 10 mm and a maximum width of less than approximately 5 mm.
34. (Original) The device of claim 25, wherein the means for attaching is degradable to permit detachment of the device housing from the tissue and passage of the device through the gastrointestinal tract.

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35. (Original) The device of claim 25, wherein the means for generating the stimulation waveform generates a stimulation waveform selected to suppress one or more symptoms including at least one of nausea and vomiting.
36. (Original) The device of claim 25, wherein the means for generating the stimulation waveform generates a stimulation waveform selected to suppress one or more symptoms secondary to at least one of gastroparesis, functional dyspepsia, chemotherapy, post-operative ileus, and pregnancy.
37. (Original) The device of claim 25, wherein the means for generating the stimulation waveform generates a stimulation waveform with an amplitude in a range of approximately 0.1 mA to 10 mA, a frequency in a range of approximately 10 Hz to 250 Hz, a pulse width in a range of approximately 100 microseconds to 1000 microseconds, an on duty cycle in a range of approximately 0.1 seconds to 0.5 seconds, and an off duty cycle in a range of approximately 1 second to 10 seconds.
38. (Original) The device of claim 25, wherein the means for generating the stimulation waveform generates a stimulation waveform with an amplitude of approximately 5 mA, a frequency of approximately 14 Hz, a pulse width of approximately 330 microseconds, an on duty cycle of approximately 0.1 seconds, and an off duty cycle of approximately 5 seconds.
39. (Currently amended) A method for electrical stimulation of a gastrointestinal tract of a patient, the method comprising:
- placing an electrical stimulation device having a device housing at a target location with the gastrointestinal tract;
  - attaching a the device housing to tissue at the target location with a fixation structure mounted on, or contained at least partially within, to the device housing wherein the fixation structure comprises an expandable frame mounted on the device housing that is expandable radially outward to contact a lumen wall within the gastrointestinal tract, a cavity formed within the device housing, or one or more barbed hooks extending from within the device housing to penetrate gastrointestinal tissue;

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generating an electrical stimulation waveform with an electrical pulse generator mounted within the device housing wherein the pulse generator is powered by a power source mounted within the device housing; and

delivering the electrical stimulation waveform to the gastrointestinal tract with electrodes coupled to the pulse generator and mounted to the device housing.

40. (Original) The method of claim 39, wherein placing the stimulation device includes endoscopically placing the stimulation device with an endoscopic delivery device introduced into an esophagus of the patient.

41. (Currently amended) The method of claim 39, wherein the fixation structure comprises the cavity formed within the device housing and attaching the device housing includes applying vacuum pressure to a the cavity within the device housing to draw tissue into the cavity, and advancing a pin to penetrate the tissue within the cavity.

42. (Original) The method of claim 41, wherein the pin forms one of the electrodes.

43. (Original) The method of claim 39, wherein attaching the device housing includes penetrating gastrointestinal tissue with one or more barbed hooks.

44. (Original) The method of claim 43, wherein the barbed hooks form at least one of the electrodes.

45. (Cancel) The method of claim 39, wherein attaching the device housing includes penetrating gastrointestinal tissue with a screw-like extension that extends from the device housing to penetrate gastrointestinal tissue.

46. (Cancel) The method of claim 45, wherein the screw-like extension forms one of the electrodes.

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47. (Currently amended) The method of claim 39, wherein attaching the device housing includes expanding ~~the an~~ expandable frame radially outward to contact a lumen wall within the gastrointestinal tract, ~~the device housing being mounted to the expandable frame.~~
48. (Cancel) The method of claim 39, further comprising powering the pulse generator with a power source mounted within the device housing.
49. (Currently amended) The method of claim ~~39~~ 48, wherein the power source includes a substantially disc-shaped battery.
50. (Original) The method of claim 39, wherein the fixation structure is degradable to permit detachment of the device housing from the tissue and passage of the device through the gastrointestinal tract.
51. (Original) The method of claim 39, wherein the stimulation waveform has parameters selected to suppress one or more symptoms including at least one of nausea and vomiting.
52. (Original) The method of claim 39, wherein the stimulation waveform has parameters selected to suppress one or more symptoms secondary to at least one of gastroparesis, functional dyspepsia, chemotherapy, post-operative ileus, and pregnancy.
53. (Original) The method of claim 39, wherein the stimulation waveform has an amplitude in a range of approximately 0.1 mA to 10 mA, a frequency in a range of approximately 10 Hz to 250 Hz, a pulse width in a range of approximately 100 microseconds to 1000 microseconds, an on duty cycle in a range of approximately 0.1 seconds to 0.5 seconds, and an off duty cycle in a range of approximately 1 second to 10 seconds.
54. (Original) The method of claim 39, wherein the stimulation waveform has an amplitude of approximately 5 mA, a frequency of approximately 14 Hz, a pulse width of approximately 330 microseconds, an on duty cycle of approximately 0.1 seconds, and an off duty cycle of approximately 5 seconds.



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55. (Original) The method of claim 39, further comprising delivering the electrical stimulation waveform to treat symptoms of nausea and vomiting following chemotherapy.

56. (Original) The method of claim 39, further comprising delivering the electrical stimulation waveform to treat symptoms of nausea and vomiting following surgery.